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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,510	10/27/2003	Eugene M. Breznock		2672

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EXAMINER

HAND, MELANIE JO

ART UNIT PAPER NUMBER

3761

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/694,510

Applicant(s)

BREZNOCK ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/2/05
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-15 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-15 and 21-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group II, claims 9-15 in the reply filed on December 2, 2005 is acknowledged.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-15, 21-26 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giba et al (U.S. Patent No. 5,997,526) in view of Baer (U.S. Patent No. 5,419,776).

With respect to **Claim 9**: Giba teaches a shape memory catheter for insertion into a body cavity. In operation, the catheter, which is comprised of a handle and an elongated catheter tube having a distal tip portion, is inserted into a patient, interpreted as encompassing insertion into

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having a distal tip portion, is inserted into a patient, interpreted as encompassing insertion into an incision. The distal tip 6 is guided via x-ray or the like to its destination, where the distal tip 6 is selectively remotely activated to assume a pre-programmed curved shape from a normally linear straight configuration. Giba does not teach a opening or closing a pre-attached valve to control influx of fluid, air or contaminants.

Baer teaches a pneumothorax treatment device comprising a conduit 6 that is configured for attachment to a one-way valve 5, 90-degree elbow 7 and catheter or needle 61. The first end 35 of catheter 6 is secured via friction fit to the intake port 26 of valve 5 and the catheter 61 is in flow communication with elbow 7 and valve 5. Valve 5 also has a suction port 24 so that it may supply and regulate the flow of suction or drainage fluid through the conduit 6 to prevent pneumothorax, therefore it would be obvious to modify catheter of Giba to be attachable to a one-way valve as taught by Baer.

With respect to **Claim 10**: Giba teaches that bending of the distal portion 6 is controlled by buttons 46 on handle 2 of the device. ('526, Col. 8, lines 18-21)

With respect to **Claim 11,12**: Giba teaches that various portions of the distal tip 6 are bent when sensor wires 42 threaded through holes in tip 6 and extend from electrical contact plates 8 through the length of the catheter 4 to the handle 2 where electrical signals and the resulting retraction of the corresponding portion of the tip 6 are actuated. ('526, Col. 5, lines 48-67)

With respect to **Claim 13**: Please see the rejections of claims 9 and 13 in addition to the following: Giba teaches inserting an additional tube through catheter 4 for removal of tissue and fluid, but does not teach a needle. Baer teaches a needle 61 with body-invasive tapered lumen

66 ('776, Fig. 3) that is capable of detachment from luer lock 8 once conduit 6 is in place. Baer teaches that this device is suitable for pneumothorax treatment, therefore it would be obvious to modify the device of Giba, also suited for insertion into the thoracic cavity so as to include a removable needle with a tapered point as taught by Baer as opposed to a removal tube threaded through catheter 4.

With respect to **Claim 14**: Giba does not teach a tapered trocar. Baer teaches a conduit connected to an elbow 7 that is operatively connected to a luer lock lug receptacle 8 with lugs 60 that secure the needle 61 in place. This assembly enables use for an emergency pneumothorax prevention procedure ('776, Col. 4, lines 31-41), therefore it would be obvious to modify the catheter 4 taught by Giba to be pre-mounted on a trocar needle as taught by Baer for emergency use.

With respect to **Claim 15**: The bent shape of distal portion 6 of catheter 4 taught by Giba enables retention of the catheter in place. ('526, Fig. 6)

With respect to **Claim 21,22**: Please see the rejections of claims 9 and 13 as they collectively address all of the limitations of claim 21,22.

With respect to **Claim 23**: Giba teaches a lumen inserted through catheter 4 for drainage and therefore the two are operably connected, but not by means of a sideport, which would simply be an alternate method of accomplishing operable connectivity between the catheter and drainage lumen. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA

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1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

With respect to **Claim 24,31**: Giba does not teach a valve at the proximal end of catheter 4. Baer teaches a one-way valve 5 connected to conduit 6 at a proximal end with respect to a patient. Baer teaches that this valve regulates suction flow to assist in preventing pneumothorax, therefore it would be obvious to modify the device of Giba so as to be connectable to a valve as taught by Baer, since the device of Giba is also suited for insertion into the thoracic cavity.

With respect to **Claim 25**: Neither Giba nor Baer teaches a valve preattached prior to removal from its packaging, however Examiner asserts that since the valve 5 taught by Baer is capable of being attached via friction fit to conduit 6, that Baer teaches that the valve can be attached prior to packaging and thus also prior to removal from said packaging.

With respect to **Claim 26**: Giba does not teach a tapered trocar for catheter 4. Baer teaches a lumen 66 that is unitary in structure with needle 61. Since Baer teaches that needle 61 has a tubular structure and that it can be substituted with a catheter also having a tapered lumen 66, Examiner asserts that lumen 66 is comprised of a flexible material and said tapered lumen is capable of expanding an incision or a conduit in the patient's body.

With respect to **Claim 33**: Giba does not teach a valve. Baer teaches a valve but does not explicitly teach that it is normally closed. However, since Baer teaches that the suction that the valve regulates is not continuously attached, Examiner asserts that the valve is normally closed.

Claims 27-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giba ('526) in view of Baer ('776) as applied to claims 9-15, 21-26 and 31 above, and further in view of Amirana (U.S. Patent No. 5,897,531).

With respect to **Claim 27,28**: The combined teaching of Giba and Baer does not teach an extracorporeal fixation device located distally along a catheter. Amirana teaches an adhesive surgical retaining device intended for retaining a catheter in place and prevent axial and rotational movement of a catheter during a pneumothorax treatment procedure. The device comprises planar field 102 comprised of adhesive tape located distally along the tube adjacent the thoracic wall of a patient. Stationary support 105 comprising an adherent member 106 and base support 108, and stationary support 105 holds a catheter 104 in place during the procedure. ('531, Fig. 1) ('531, Col. 5, lines 10-19,32-35) Amirana teaches that this device maintains a fixed relationship of the catheter 104 with respect to the thoracic wall of a patient when desired but by choice ('531, Col. 5, lines 2-8), therefore it would be obvious to modify the device of the combined teaching of Giba and Baer so as to be capable of being fixed in position during a procedure when desired as taught by Amirana.

With respect to **Claim 29**: The bent distal tip 6 taught by Giba acts as an intracorporeal fixation device.

With respect to **Claim 30**: Giba does not teaches the use of an inflated balloon, however an inflated balloon provide the equivalent result to a bent distal tip, which is to fix a catheter in place, therefore a balloon is simply an alternate means of fixation, and therefore it would be

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obvious to replace the bent distal tip with, or to add to the distal tip, a balloon port and inflatable balloons, as balloon catheters are well-known in the art. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giba ('526) in view of Baer ('776) and further in view of Amirana (U.S. Patent No. 5,897,531) as applied to claims 27-30 and 33 above, and further in view of Dodge et al (U.S. Patent No. 4,036,231).

With respect to **Claim 32**: The combined teaching of Giba and Baer and Amirana does not teach a valve that is selectively closed via the expansion of an open-celled foam. Dodge teaches a thoracic drainage unit wherein a defoaming member 66 comprised of open-celled polyurethane foam that expands to occlude tube 46, preventing any blood foam from entering and fouling the vacuum chamber. ('231, Col. 3, lines 37-68) Since the device of the combined teaching of Giba and Baer and Amirana is suited for use in the thoracic cavity of a patient and is capable of draining fluid, specifically blood, it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching so as to include an open-celled foam that protects the vacuum source as taught by Dodge.



**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand  
Examiner  
Art Unit 3761

MJH

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

